REMARKS

This Reply is responsive to the Office Action mailed 12/06/2005 and is accompanied by a petition for a two-month extension of time along with an authorization to charge the required statutory fee.

The specification were objected to and are amended as required. No new matter was added.

Claims 17-24 were pending at the time of the Office Action. All claims were rejected. Claims 17-24 are amended herein. New claims 25-28 have been added No new matter has been added.

Priority to abandoned Application No. 09/988,869 and its status in included with the amendment to the specification as required by the Examiner.

All inventors are common to both applications and every inventor is an inventor of at least one of the claims of the instant application.

The title has been changed to "Utilization of Rhinologically Active Substances" to clearly indicate the claimed invention.

4-6 The abstract and portions of the description were amended to indicate that the compounds are alicyclic compounds. Applicant points out that although the rhinologically active compounds are alicyclic, the ether portion is acyclic where the ether linkage does not reside within a ring of the compounds. Hence the compound is alicyclic but it is an acyclic ether. This is an important feature of these compounds that distinguish them from compounds, such as eucalyptol, where the ether functionality is part of a ring and is a cyclic ether as well as an alicyclic compound. The use of the terms acyclic ether was to permit the ready distinction of the location of the ether in the molecule. The abstract and paragraph [00013] of the description are amended to use the term alicyclic compound and to use phrases to indicate that it is an ether where the ether linkage is not within the ring. This is an important difference as methods of preparing these compounds, as indicated in paragraph [00018], for acyclic ethers differs from that for an ether linkage within the ring. Paragraph [00018] was amended by removing the word acyclic. All changes are required because of the removal of the term acyclic from the text and are not an addition of new matter.

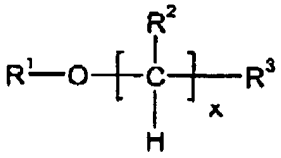
Moving now to the claims, claims 20, 23, and 24 are rejected based on U.S.C. 112, paragraph 2, as being indefinite.

9-12 Claim 20 is amended to recite "a preparation comprises 0.0001 to 10% by weight of said rhinologically active substance", claim 23 is amended to recite "The process according to Claim 22", and claim 24 is amended to recite "1-(3,3-dimethylcyclohexyl)ethyl methyl ether". These corrections were made as correctly required by the Examiner.

Amended independent claim 17 recites:

A process for creating a clearing feeling in a pharyngeal cavity and nasal cavity comprising the step of:

administering to a subject in need thereof an effective amount of a preparation comprising a rhinologically active substance with a formula:



wherein

x is 0 or 1,

R^1 denotes an alkyl group having 1 to 4 carbon atoms,

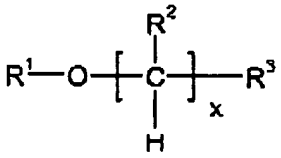
R^2 denotes a methyl or ethyl group,

R^3 denotes a monocyclic aliphatic carbon system having 5,6,7 or 8 carbon atoms that can be unsubstituted or substituted with further alkyl groups having 1 to 4 carbon atoms or alkenyl groups having 2 to 4 carbon atoms, whereby said clearing feeling in said pharyngeal cavity and nasal cavity is created.

New claim 29 is added to indicate the specific use in a preparation to be ingested as a solid or a liquid rather than as a gas or smoke:

A process for creating a clearing feeling in a pharyngeal cavity and nasal cavity comprising the step of:

administering to a subject in need thereof an effective amount of a preparation to be ingested as a solid or a liquid comprising a rhinologically active substance with a formula:



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R^3 denotes a monocyclic aliphatic carbon system having 5,6,7 or 8 carbon atoms that can be unsubstituted or substituted with further alkyl groups having 1 to 4 carbon atoms or alkenyl groups having 2 to 4 carbon atoms, whereby said clearing feeling in said pharyngeal cavity and nasal cavity is created.

Examiner correctly pointed out that the invention was directed to alicyclic compounds, aliphatic cyclic compounds, and Claim 17 stands amended to clarify that the alicyclic compound was saturated. New claim 29 recites a preparation to be ingested as a solid or liquid to distinguish from preparations that are to be inhaled in a gas or smoke. Dependent claim 22 is amended to include the word smokeless, as the invention is for the modification of the sensory stimulation resulting from placing a solid or liquid in the mouth and nothing disclosed in the specification is directed to the inhalation of a gas or smoke. Claim one was amended to distinctly indicate that the clearing feeling was to be experienced in the pharyngeal cavity and nasal cavity. The nasal cavity is identified as the airways in paragraph [0003] and the clearing effect was identified in the description of the invention to occur in the pharyngeal cavity and airways in paragraphs [00012], [00019] and [00040] as well as Examples 2, 3, and 4. In no place in the specification is the possibility of a clearing feeling in only the pharyneal cavity or only the nasal cavity recited.

14 Turning now to rejections based on cited art, claims 17-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Jamboe et al. US 3,128,772. According to the Examiner:

Jarboe et al. teach flavoring additives for tobacco products which impart a cooling sensation to the smoker when the tobacco is smoked (see entire disclosure, in particular column 1, lines 25-30). The additives are menthyl ethers (see column 1, line 40 to column 5, line 55). The menthyl ether content is between 0.01 to 1.0% by weight of the smoking tobacco product (see column 5, lines 59-62).

Jarboe et al. requires administration of the ethers via smoking and the compounds are taught to be volatile and pyrolyzed at the very high temperature of the burning tobacco in the act of smoking. Everything disclosed in the claims and specification of Jarboe et al. pertains to the delivery of compounds via smoking. The amended claimed invention requires that they have sufficient activity at approximately body temperature or lower to be delivered to the pharyngeal cavity and the nasal cavity from an ingested liquid or solid. Claim 22 is amended to distinctly point out the use of the preparation in a smokeless tobacco product. As Jarboe et al. is directed to a smoking tobacco product where the compounds are delivered with a gaseous vehicle at an elevated temperature with accompanying pyrolysis, it can not anticipate a process for delivering a preparation where the rhinologically active substance is not delivered by smoking. Applicant respectfully requests the allowance of amended claims 17-22.

15 Claims 17, 18, and 20-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Garlick, Jr. et al (US 5,695,746) or Pensak et al. (US 3,947,579A). According to the Examiner:

Garlick, Jr. et al. teach a liquid dentifrice comprising anethole, which is a compound having the claimed formula, wherein the dentifrice is disclosed to maintain the cooling and freshness attributes of menthol without bitterness or burning (see entire disclosure, in particular claims 1-14). The anethole compounds of Garlick, Jr. et al. would inherently provide the cooling and refreshing feeling to eh pharyngeal or nasal cavity, since the compounds of Garlick, Jr. et al. have the same chemical formula and are utilized in the same manner, i.e., orally.

Pensak et al. teach a mouthwash having a stimulating and refreshing taste of lemon (see entire disclosure, in particular column 1, lines 8-15). Materials useful in mouthwash include anethole, which is a compound having the claimed formula (see column 1, lines 48-68).). The anethole compound of Pensak et al. would inherently provide the cooling and refreshing feeling to eh pharyngeal or nasal cavity, since the compounds of Pensak et al. have the same chemical formula and are utilized in the same manner, i.e., orally.

Amended claim 17 clearly points out that the rhinologically active substance is a saturated compound with an ether functionality external to the ring of the alicyclic compound. Garlick, Jr. et al. teaches the use of anethole. Anethole is an aromatic compound and not a

saturated alicyclic compound of the amended claim 17. Pensak et al. also teaches anethole. As none of the ethers of the amended claims are taught in either of the references, there can be no anticipation of amended claims 17, 18, and 20-23. Applicant respectfully requests the allowance of amended claims 17, 18, and 20-23.

16 Claims 17, 18 and 20-22 are rejected under 35 U.S.C. 102(e) as being anticipated by Hanke (U.S. Patent 6,231,900 B1). According to the Examiner:

> Hanke teaches a confectionary product and preparation having the claimed formula, wherein R^1 is as claimed, R^3 is an alkyl substituted cyclohexyl and x is 0 (see entire disclosure, in particular column 1, lines 10-30; column 2, lines 4-6; column 2, line 26 to column 3, line 15; column 4, lines 1-24; column 7, lines 41-45 and examples 1 and 2). The confectionary product is disclosed as being in various forms including hard and soft candies, chewing gum and pastilles (see column 2, lines 32-35). The cooling agent is present in an amount from about 0.01 to about 15% (see column 5, lines 41-45). The products have good throat soothing properties (see column 1, lines 5-9).

Applicants respectfully submit that Hanke does not teach the claimed compounds of the present invention. The only ethers structure in Hanke is vaguely defined, where R_5 has an "optionally hydroxy substituted aliphatic radical containing up to 25 carbon atoms, preferably up to 5 carbon atoms" (Hanke column 4, lines 16-16). One of ordinary skill in the art is required to discern whether the "optionally" term means that a hydroxy substituent is required and can there only be one hydroxy substituent, whether the hydroxy substituent can be at any carbon, and whether there can be more than one hydroxy substituent among a host of possibilities. To understand this vaguely defined structure one can only look at the specific examples disclosed to discern what is meant. The ether compounds specifically mentioned in Hanke are Takasago 10, where R^1 is 3-1-menthoxypropane-1,2-diol (Hanke column 4, lines 21-24) referred to as a monoglyceride of menthol, and, perhaps, mentholated sucrose (Example 2) although no disclosure is made that this is an ether. Both of these compounds necessarily contain multiple hydroxy substituted aliphatic carbons. Thus one of ordinary skill in the art can only reasonably

conclude that the modifier "optionally" indicates that one or more hydroxy groups are substituted at any of the carbons, as this is the only interpretation that is consistent with any of the specifically disclosed ethers. Hanke does not teach the clearing feeling in the nasal cavity, disclosing only a cooling effect in the throat and mentions nothing about any sensation in the nasal cavity where the compounds of the present invention produced a dramatic effect. This is consistent with the lack of volatility one of ordinary skill in chemistry would anticipate for the ethers and all other compounds disclosed by Hanke to give the cooling sensation to a sore throat. Hence, Hanke does not anticipate the present invention as it does not teach the rhinologically active substances and does not teach the clearing feeling in the nasal cavity. Applicants respectfully request that amended claims 17, 18, and 20-22 be allowed.

20 Claims 17 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hanke (US 6,231,900 B1). According to the Examiner:

Hanke disclose the invention as described above but fail to specifically disclose the compounds of claim 19. However, although not explicitly taught the menthyl ether compounds of the instant claims are clearly suggested by Hanke.

The compounds of amended claim 19 all permit a clearing feeling in the nasal cavity, an effect that is not taught by Hanke. Furthermore, not only are the compounds of claims 19 not taught by Hanke, the compounds of the formula of claim 17 are not disclosed. As Hanke only teaches ethers that have hydroxy groups to give a cooling sensation to the throat, it does not suggest ethers where the hydroxy groups are absent and provides a clearing feeling to the nasal cavity as well as the pharyngeal cavity. Hence, Hanke does not suggest the ethers of the amended claims. Applicants respectfully request that amended claims 17 and 19 be allowed.

21. Claims 17, 18, and 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thomas et al. (US 3,993,604). According to the Examiner:

Thomas et al. teach alicyclic compounds having the claimed formula, wherein R^1 is as claimed, R^2 is hydrogen, R^3 is an alkyl or alkenyl substituted cyclohexyl and x is 1 (see column 1, lines 6-45; column 3, lines 15-41; and examples 6 and 7). The claimed method is inherently taught since the compounds of Thomas et al. when digested in the foodstuffs disclosed by Thomas et al. would necessarily perform the claimed method.

The alicyclic compounds of Thomas et al. differ from the claimed compounds in that R^2 is hydrogen instead of methyl as claimed.

One having ordinary skill in the art at the time the invention was made would have found the instant invention obvious over the teachings of Thomas et al. since, it is well established that the substitution of methyl for hydrogen on a known compound is not a patentable modification absent unexpected or unobvious results. *In re Lincoln*, 126 USPQ 477, 53 USPQ 40 (CCPA 1942); *In re Druey*, 319 F.2d 237, 138 USPQ 39 (CCPA 1963); *In re Lohr*, 317 F.2d 388, 137 USPQ 548 (CCPA 1963); In re Hoehsema, 399 F.2d 269, 158 USPQ 598 (CCPA 1968); *In re Wood*, 582 F.2d 638, 199 USPQ 137 (CCPA 1978); *In re Hoke*, 560 F.2d 436, 195 USPQ 148 (CCPA 1977); *Ex parte Faugue*, 121 USPQ 425 (POBA 1954); *Ex parte Henkel*, 130 USPQ 474, (POBA 1960).

Thomas et al. further differ from the instant invention in that Thomas et al. fail to teach the use of the compound in amounts less than 0.05%.

One having ordinary skill in the art at the time the invention was made would have found the instant invention obvious over the teachings of Thomas et al. since, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955).

Although the substitution of a methyl group for a hydrogen is not inherently a patentable modification, evidence that the modification gives a different expression to a property is an unobvious result and is therefore patentable. This is the situation between the compounds of Thomas and the present invention. The rhinoligically active substances of the present invention produce a refreshing clearing feeling and "exhibit fresh, etheral, minty, cooling, sweet and fruity flavor notes". (paragraph [00019]) In contrast, the compounds of Thomas, compounds Ib, "may be characterized by a green, slightly flowery and fruity gustative note. The dominate characteristic of the compounds of Thomas is the flowery note "characterized by an original flowery note reminiscent in some instances of that of cyclamen or lily of the valley" (Thomas column 2 line 69 to column 3 line 2). The dominate fresh, etheral, minty, and cooling notes of the present invention are absent from the compounds of Thomas. Hence, the presence of a methyl or ethyl group in the present invention does give different unobvious results with respect to flavor and odor that are not suggested by Thomas. Thomas reports significant testing on its compounds yet never noted the clearing feeling that is a very dramatic characteristic of the compounds with methyl and ethyl substituents for R^2 of the present invention. As the rhinological properties of odor and flavor in the present invention are disclosed to be significantly different from those properties disclosed in Thomas, and since Thomas does not teach or suggest providing a clearing feeling in spite of a significant amount of testing, it is logically inconsistent to conclude that the clearing feeling imparted by the compounds of the present invention are inherent to the compounds of Thomas. Hence, Thomas does not teach or suggest the claimed method and the present invention is unobvious. Applicant respectfully requests that the rejection be withdrawn and that amended claims 17, 18, and 20-22 be allowed.

Applicants have made every effort to present claims which distinguish over the cited art, and it is believed that all claims are in condition for allowance. However, Applicants invite the Examiner to call the undersigned if it is believed that a telephonic interview ((561) 653-5000) would expedite the prosecution of the application to an allowance. The Commissioner for Patents is hereby authorized to charge the fee for a two month extension of time and any deficiency in fees due or credit an excess in fees with the filing of the papers submitted herein during prosecution of this application to Deposit Account No. 50-0951.

Respectfully submitted,
AKERMAN SENTERFITT

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